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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent Application of: ) Group Art Unit: To Be Assigned  
CUNNINGHAM *et al.* )  
Serial No. 09/954,586 ) Examiner: To Be Assigned  
Filed: September 11, 2001 ) Atty. Docket No. GP116-03.UT  
For: COMPOSITIONS, METHODS AND KITS )  
FOR DETERMINING THE PRESENCE )  
OF CRYPTOSPORIDIUM PARVUM )  
ORGANISMS IN A TEST SAMPLE )

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. § 1.97(b) & (c)**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Applicants bring to the Examiner's attention the references listed on the enclosed form PTO/SB/08 (two copies) for consideration in connection with the examination of the above-identified application. A copy of each cited reference is enclosed herewith.

This Information Disclosure Statement is being submitted under 37 C.F.R. § 1.97(b) before the mailing date of a first Office action on the merits.

If Applicants are mistaken, and a first Office action on the merits was mailed on or before the certified date of mailing indicated below, then Applicants request that this Information Disclosure Statement be treated as a submission under 37 C.F.R. § 1.97(c) and that the fee due under 37 C.F.R. § 1.17(p) be charged to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

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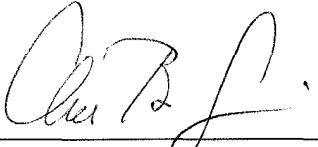
Serial No. 09/954,586  
Atty. Docket No. GP116-03.UT

Applicants respectfully request that the Examiner indicate consideration of each cited reference by returning a copy of the enclosed form PTO/SB/08 with the Examiner's initials or other appropriate marks.

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date indicated below with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

Respectfully Submitted,

Date: January 4, 2002

By:   
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	09/954,586
				Filing Date	September 11, 2001
				First Named Inventor	CUNNINGHAM et al.
				Group Art Unit	To be assigned
				Examiner Name	To be assigned
				Attorney Docket Number	GP116-03.UT
Sheet	1	of	4		

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Sheet 1 of 6

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Application Number 09/954,586

**Filing Date** **September 11, 2001**

First Named Inventor CUNNINGHAM et al.

### Group Art Unit

Examiner Name	To be assigned
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Examiner Name \_\_\_\_\_

Attorney Docket Number

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Office <sup>3</sup>	Number <sup>4</sup>			
		EP	0652974	B1	Minister of Agr., Fisheries & Food of the U.K.	05-17-1995
		WO	9402635	A1	Minister of Agr., Fisheries & Food of the U.K.	02-03-1994
		WO	9404681	A1	Istituto Superiore DI Sanita et al.	03-03-1994
		WO	9634978	A1	Mac-Quarie Research Limited et al.	11-07-1996
		WO	9640926	A2	The Board of Regents of the University of Oklahoma	12-19-1996
		WO	9702281	A1	Murdoch University	01-23-1997
		WO	9703362	A1	ImmuCell Corporation	01-30-1997
		WO	9708204	A1	MacQuarie Research Ltd et al.	03-06-1997
		WO	9742349	A1	Metropolitan Water District of Southern California	11-13-1997
		WO	9804675	A2	Pall Corporation	02-05-1998

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Application Number 09/954,586

**Filing Date** **September 11, 2001**

First Named Inventor **CUNNINGHAM et al.**

Group Art Unit **To be assigned**

Examiner Name    **To be assigned**

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### OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		AWAD-EL-KARIEM et al., "Detection and species identification of Cryptosporidium oocysts using a system based on PCR and endonuclease restriction", Parasitology, July 1994, p. 19-22, vol. 109, Cambridge University Press, UK	
		BALATBAT et al., "Detection of Cryptosporidium parvum DNA in Human Feces by Nested PCR", J. Clin. Microbiol., July 1996, p. 1769-1772, vol. 34, no. 7, American Society of Microbiology, US	
		CARRAWAY et al., "Genetic Markers Differentiate C. parvum Isolates", J. Eukaryot. Microbiol., Sept.-Oct. 1994, p. 26S, vol. 41, no. 5, Allen Press Inc., US	
		CHRISP et al., "Similarities and differences between DNA of cryptosporidium parvum and C. wrairi detected by the polymerase chain reaction", Folia Parasitol., 1994, p. 97-100, vol. 41, no. 2, Czech Academy of Sciences, CZ	
		DEERE et al., "Rapid method for fluorescent in situ ribosomal rna labeling of cryptosporidium parvum", J. Appl. Microbiol., Nov. 1998, p. 807-818, vol. 85, no. 5, Blackwell Science Limited, UK	
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### OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

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		MORGAN et al., "Phylogenetic Analysis of Cryptosporidium Isolates from Captive Reptiles Using 18S rDNA Sequence Data and Random Amplified Polymorphic DNA Analysis", J. Parasitol., June 1999, p. 525-530, vol. 85, no. 3, American Society of Parasitologists, US	
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		ZHU et al., "Direct Isolation of DNA from Patient Stools for Polymerase Chain Reaction Detection of Cryptosporidium parvum", J. Infect. Dis., May 1998, p. 1443-1446, vol. 177, no. 5, University of Chicago Press, US	

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